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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,637

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Giuseppe Giannini

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EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

01/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,637	Applicant(s) GIANNINI ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008 and 29 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 19, 23, 24 and 26-29 is/are rejected.
- 7) ☒ Claim(s) 17, 18 and 20-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/24/08, 10/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on Oct. 24, 2008, the applicants have filed RCE; amended claims 20, 22 and 27 and furthermore, have added new claims 28 and 29.

2. In a supplemental amendment filed on Oct. 29, 2008, the applicants have canceled claim 25 and amended claims 28 and 29.

3. Claims 15-24 and 26-29 are now pending in the application.

Response to Arguments

4. Applicant's arguments filed on Oct. 24, 2008 have been fully considered but they are not persuasive regarding enablement rejection of instant claims 26-28. The examiner agrees with the applicants arguments regarding provisional ODP rejections that the instant compounds differ from those of three cited applications. In regard to enablement rejection, the examiner does not agree with the applicants arguments that the specification is enabling for treating every known cancer, every known parasite and every known virus disease. Applicant's attention is drawn to the article by Horwitz (cited on applicants form 1449) who did not observe any effect of Camptothecin on poliovirus. It would require undue experimentation to demonstrate the efficacy of instant compounds for inhibiting every known cancer cell line, every known parasite and every known virus and hence their utility for treating these disease conditions. However, it is of

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note that the instant specification is enabling for treating non-microcytoma lung cancer and gastric cancer with the instant compounds.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 28 and 29 recite the limitation "The method wherein said cancer" in claim 15.

There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 15, 16, 19, 23, 24 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Dallavalle (J. Med. Chem. , cited on applicant's form 1449).

Dallavalle discloses Novel 7-oxyiminomethyl derivatives of camptothecin with potent in vitro and in vivo antitumor activity. The compound 22 (see table 1 on page 3265) anticipates the instant claims when m represents 0 and the protective group for variables Ri, Rii or Riii for nitrogen is represented by an alkyl group in the instant compounds of formula (I).

8. Claims 15, 16, 19, 23, 24 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Penco (U.S. Patent 6,242,457).

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Penco discloses Camptothecin derivatives having antitumor activity. The compounds of formula (I) disclosed in column 5 where R₄ represents polyaminoalkyl group (see col. 5, line 45 and col. 6, line 65 to col. 7, line 4) by penco anticipate the instant claims when m represents 0 and the protective group for variables R_i, R_{ii} or R_{iii} for nitrogen is represented by an alkyl group in the instant compounds of formula (I).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 15, 16, 19, 23, 24 and 26-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 11 and 14-16 of U.S. Patent No. 6,242,457. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds claimed in the cited patent anticipate the instant claims when m represents 0 and the protective group for

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variables Ri, Rii or Riii for nitrogen is represented by an alkyl group in the instant compounds of formula (I).

11. Claims 15, 16, 19, 23, 24 and 26-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5 and 13-17 of U.S. Patent No. 7,105,492. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds claimed in the cited patent anticipate the instant claims when m represents 0 and the protective group for variables Ri, Rii or Riii for nitrogen is represented by an alkyl group in the instant compounds of formula (I).

Allowable Subject Matter

12. Claims 17, 18 and 20-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/
Primary Examiner, Art Unit 1625